ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

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The Effect of Telephone Follow-Up System on Exercise Compliance and Disease Activity in Ankylosing Spondylitis Patients-an Open-Label: Randomized Controlled Trial

Ankilozan Spondilit Hastalarında Telefon Takip Sisteminin Egzersiz Uyumu ve Hastalık Aktivitesine Etkisi-Açık Etiketli: Randomize Kontrollü Bir Çalışma

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ABSTRACT Objective: Exercise therapy in ankylosing spondylitis (AS) is strongly recommended by treatment guidelines, but adherence and compliance with exercise therapy in AS are low. Although studies have shown that the telephone follow-up system increases treatment compliance in some chronic diseases, data showing the effect of the telephone follow-up system in AS are very limited. This study aimed to examine the effect of the telephone follow-up system on disease activity and exercise treatment compliance in patients with AS. **Material and Methods:** In this study, a randomized controlled study was designed comparing 24 AS patients with a telephone follow-up system and 29 control patients diagnosed with AS. Patients were followed up for 12 weeks. Weekly exercise durations, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores, and weekly analgesic amounts were clinical outcome measures. **Results:** There was no significant increase in exercise duration, no significant decrease in BASDAI score, or the amount of analgesic in the control group. However, there was a significant increase in exercise duration, a significant decrease in the BASDAI score, and the amount of analgesic at the end of 12 weeks in the telephone follow-up system group compared to the baseline. **Conclusion:** The telephone call follow-up system effectively increases exercise duration and decreases BASDAI score and analgesic use in AS patients.

Keywords: Ankylosing spondylitis; exercise; exercise compliance; BASDAI; telephone follow-up system

ÖZET Amaç: Ankilozan spondilitte (AS) egzersiz tedavisi, tedavi kılavuzlarında şiddetle tavsiye edilmektedir ancak AS'de egzersiz tedavisine uyum düşüktür. Yapılan araştırmalar, bazı kronik hastalıklarda telefon takip sisteminin tedaviye uyumu artırdığını gösterse de AS'de telefon takip sisteminin etkisini gösteren veriler oldukça kısıtlıdır. Bu çalışmada, AS'li hastalarda telefon takip sisteminin egzersiz tedavi uyumuna ve hastalık aktivitesine etkisinin incelenmesi amaçlanmıştır. **Gereç ve Yöntemler:** Bu çalışma, telefon takip sistemi olan 24 AS hastası ile AS tanısı alan 29 kontrol hastasının karşılaştırıldığı randomize kontrollü bir çalışma olarak tasarlandı. Hastalar 12 hafta boyunca takip edildi. Haftalık egzersiz süreleri, Bath Ankilozan Spondilit Hastalığı Aktivite İndeksi (BASHAİ) skorları ve haftalık analjezik miktarları klinik sonuç ölçütleriydi. Bulgular: Kontrol grubunda egzersiz süresinde anlamlı artış, BASHAİ skorunda ve analjezik miktarında anlamlı azalma olmadı. Ancak telefon takip sistemi grubunda 12 hafta sonunda başlangıca göre egzersiz süresinde anlamlı artış, BASHAİ skorunda ve analjezik miktarında anlamlı azalma saptandı. Sonuç: Telefon takip sistemi AS hastalarında egzersiz süresini etkin bir şekilde artırmakta, BASHAİ skorunu ve analjezik kullanımını azaltmaktadır.

Anahtar Kelimeler: Ankilozan spondilit; egzersiz; egzersiz uyumu; BASHAİ; telefon takip sistemi

Ankylosing spondylitis (AS) is a disease characterized by inflammation of the axial skeleton and affects one in 200 individuals. Patients complain of low back pain from the early stage of the disease.[1,2] The disease usually leads to decreased spinal mobility, structural, and functional disorders in the later stages. Therefore, over time, quality of life and functional capacity decrease as well.[3-5] If inflammation in

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the axial skeleton is not controlled, new bone formation may cause spinal fusion or ankylosis.[6] Exercise and some medications are used in the treatment.[3,6,7] Clinical guidelines clearly recommend exercise for patients with AS since it improves health, increases range of motion and muscle strength, as well as reduces Bath Ankylosing Spondylitis Functional Index (BASFI) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scores, improving disease activity and physical function.[3,7-13] In addition, exercise in AS has effects such as reducing cardiovascular risk, preventing osteoporosis, and improving balance and respiratory function.[13] Despite these benefits of exercise, it has been reported that exercise compliance is low in AS patients.[9,14] Poor adherence contributes to an increase in healthcare expenditures and a considerable worsening of the disease.[9] Adherence is a primary determinant of the effectiveness of any treatment.[14] Increasing the compliance of AS patients with exercise therapy, which is an inexpensive, effective and safe treatment, may lead to an improvement in disease activity, pain level, and quality of life; thus, the need for analgesics may decrease. Therefore, it can reduce health expenses and adverse effects caused by analgesic drugs. Recently, the effects of methods such as telephone calls, telephone messages, telemedicine, and mobile health technology have been shown to increase treatment compliance in chronic diseases such as hypertension, chronic digestive diseases, and osteoporosis.[15-17] A study revealed that phone calls made after discharge increased the adaptation of patients who were followed up due to trauma to come to the next appointment.[18] It has been reported that telephone follow-up increased the patient's adherence to postoperative recommendations after the third molar surgery.[19] In addition, it has been shown that a phone call and a drug reminder program increase treatment compliance in patients with osteoporosis.[17] Moreover, systems such as telemedicine, e-mail, and eHealth have been proposed as an alternative to overcome the limitations in accessing healthcare in cases such as pandemics and quarantine.[20] However, data showing the effect of the telephone follow-up system in AS are very limited. This study aimed to examine the effect of the telephone call follow-up system on compliance with exercise therapy, BASDAI score, and analgesic use.

MATERIAL AND METHODS

This study was designed as a prospective, randomized controlled. The protocol was performed per the ethical standards set in the 2008 Declaration of Helsinki and approved by Kırşehir Ahi Evran University Medical Faculty Clinical Research Ethics Committee (date: February 11, 2020; no: 2020-02/21). All participants gave written informed consent after a comprehensive explanation of the relevant procedures. Sixty patients diagnosed with AS according to the modified New York criteria were included in the study.[21]

Inclusion criteria were being between the ages of 18-65 years and diagnosed with AS according to the modified New York criteria. Exclusion criteria included the presence of malignancy, infection, severe cardiac or respiratory disease, liver and kidney failure, and joint prostheses.

Power analysis was performed with the patients included in the study since there were no similar studies. Sixty-six patients were examined in terms of inclusion criteria. First, 60 patients who met the inclusion criteria were included in the study and randomized into 2 groups using the closed-envelope method. No additional patients were included in the study, as the sample number was 48 (24 in each group) with a 95% confidence interval and 90% power based on the statistical results of exercise durations in the 3rd month.

The patients' gender, age, weight, height, duration of symptoms, body mass index (BMI), duration of diagnosis, occupation, comorbid diseases, and medications were recorded. The number of analgesics used per week, the duration of exercise per week (in minutes), and BASDAI scores were recorded at the beginning of the study and the 12th week for all patients. BASDAI is a six-question scale that evaluates disease activity in AS patients. Patients score between 0-10 points. BASDAI scores greater than 4 indicate the presence of active disease. The Turkish version has been shown to be valid and reliable.[22-24] All evaluations were made by the same clinician.

The home exercise program, including the stretching, strengthening, range of motion, posture

exercises of the lumbar, thoracic, cervical spine, and respiratory exercises, was demonstrated to all patients practically by the same physiotherapist.[25] The given exercise program was arranged to take about 30 minutes. It was requested to be done seven days a week. In addition, written instructions were given to the patients, describing the exercises given in a simple and illustrated way. Patients were asked to note their exercise time and the number of analgesics. Patients in Group 1 were called by a medical faculty student every week for 12 weeks. The number of analgesics they used during the week and the total time (in minutes) they exercised during the week were asked and recorded. They were also reminded that their exercises are essential for the treatment of the disease. The patient, who did not answer the phone for 3 consecutive weeks, was no longer called and was excluded from the study. Group 2 was never called on the phone.

STATISTICAL ANALYSIS

Study data were evaluated using the Statistical Package for the Social Sciences version 25.0 software for Windows (IBM SPSS Statistics for Windows, Version 25.0; IBM Corp, Armonk, NY, USA). The Kolmogorov-Smirnov test revealed that the data were not normally distributed. The data obtained were presented with mean and standard deviation values. The The Mann-Whitney U was used for the independent variables and the Wilcoxon test to evaluate the relationship between dependent variables. A p value of <0.05 was considered statistically significant. Power analysis and sample size were calculated with the G*Power 3.1.9.6 software package (Franz Foul, Universitat Kiel, Germany). A mixed linear model (MLM) with random effects analysis using an unstructured covariance structure and maximum likelihood estimation was performed, and random intercepts and slopes were included. The F distribution with between-within denominator degrees of freedom was used to assess significance of fixed effects parameters.[26]

RESULTS

Of the 60 randomized patients, 6 patients in Group 1 and 1 patient in Group 2 left while the study had been initiated. As a result, the study was completed with a total of 53 patients, as 24 in the first group and 29 patients in the second group (Figure 1).

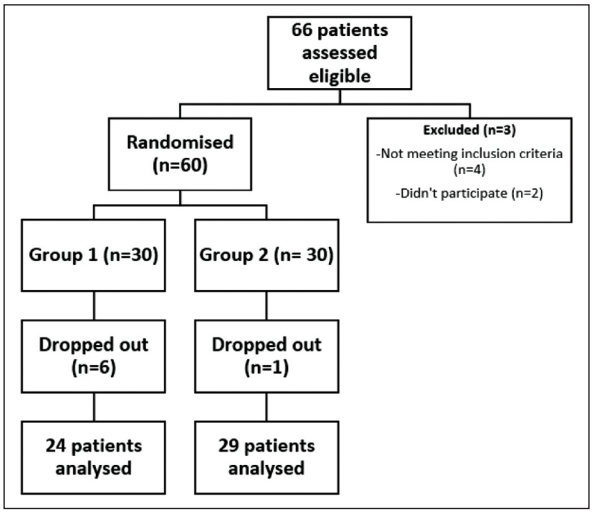

FIGURE 1: Flow of participants in this study.

There was no significant difference in both groups regarding age, gender, BMI, duration of symptom, anti-tumor necrosis factor (TNF) drug use. Duration of diagnosis was significantly higher in Group 1 ($p<0.05$) (Table 1).

There was no significant difference between Group 1 and Group 2 in terms of the mean BASDAI value at the beginning of the study. The mean BASDAI value, which was 3.93±1.58 at the beginning in Group 1, was found to be 3.23±1.25 in the 12th week, and this decrease was statistically significant

TABLE 1: Demographical and clinical characteristic of 2 groups.

	Group 1 (n=24)	Group 2 (n=29)	
	X̄±SD	X̄±SD	p value
Age	41.04±12.07	40.48±9.62	0.943
Gender	M: 18	M: 22	0.568
	F: 6	F: 7	
Male	75%	75.9%	0.953
Female	25%	24.1%	0.923
BMI	24.81±2.54	25.87±3.32	0.339
TNF	14	20	0.290
Non-TNF	10	9	0.423
Duration of symptom (years)	14.87±7.39	12.48±7.36	0.248
Duration of diagnosis (years)	9.83±6.14	7.75±5.90	**0.037**

SD: Standard deviation; BMI: Body mass index; TNF: Tumor necrosis factor; p<0.05 was statistically significant.

($p<0.01$). In Group 2, the mean BASDAI value, which was 3.12±1.22 initially, decreased to 3.11±1.29 at the 12th week, and this decrease was not statistically significant ($p=0.745$). The mean change in BASDAI score at the 12th week was higher in Group 1 ($p<0.01$).

Total exercise duration per week was statistically similar between the 2 groups at the beginning of the study. However, at the end of the study, weekly exercise duration was significantly higher in Group 1 than in Group 2. In Group 1, the average of 12 weeks was 56.62 minutes/week, and this value was significantly higher than the value at the beginning of the study (19.79 minutes/week) ($p<0.01$). In addition, the exercise duration at week 12 (the last week) in Group 1 was 70.2 minutes/week, and this value was significantly higher than the value at the beginning of the study. There was no significant difference between the baseline (26.37 minutes/week) and the 12th week (24.35 minutes/week) in Group 2 in terms of exercise duration. Mixed random linear effects analysis with the random effects of subjects showed no effect of group variable on changes in exercise durations ($F=0.018$, $p=0.895$). The exercise durations (min/week) of the groups are shown in Figure 2.

The number of analgesics taken by the patients per week at the beginning of the study was statistically similar in the 2 groups. In Group 1, the weekly total number of analgesics (3.25/week) they received in the last week of the study was statistically lower than the number at the beginning of the study (4.29/week) ($p<0.05$). In addition, the average number of analgesics per 12 weeks (3.82/week) in Group 1 was also significantly lower than the number at the beginning of the study ($p<0.05$). In Group 2, the number of analgesics taken weekly at the beginning and end of the study was statistically similar. MLM analysis revealed that decrease in weekly analgesic use was significantly higher for Group 1 ($F=5.021$, $p=0.029$). Patients receiving analgesics were taking only nonsteroidal anti-inflammatory drugs (NSAIDs) as analgesics. None of the patients received parenteral or opioid analgesics (Table 2). The weekly intake of NSAIDs according to groups are shown in Figure 3.

When we divided the patients in Group 1 into 2 groups as those who took anti-TNF drugs and those who did not, the initial exercise durations were similar. A significant increase in exercise time was found in both groups. It was found that the 12th-week exercise durations of the TNF and non-TNF groups were also statistically similar.

When we divided the patients in Group 1 into 2 groups as active (BASDAI≥4) and non-active (BASDAI<4) according to their initial BASDAI, the initial exercise times were similar. A significant increase in exercise duration was determined in both groups over time (Table 3).

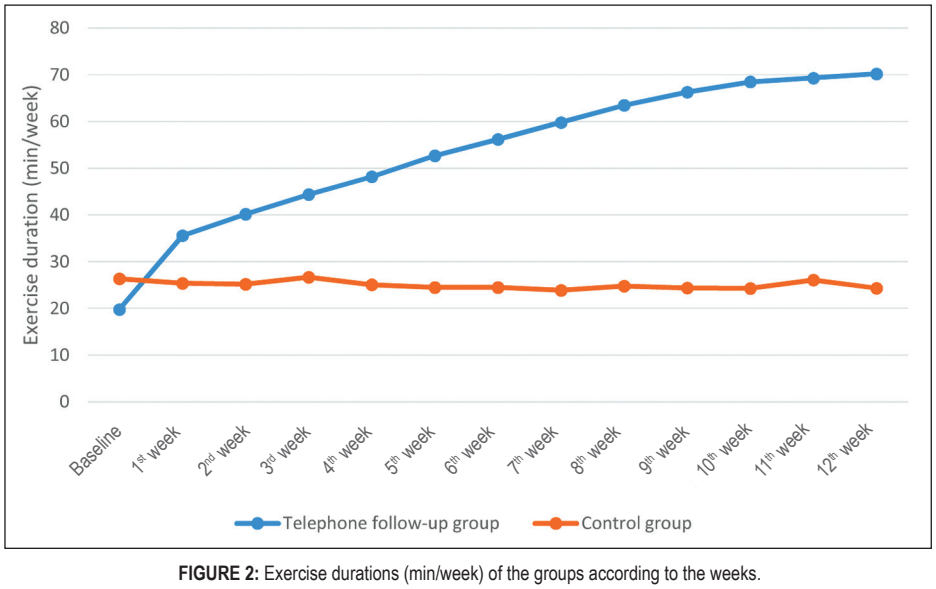

FIGURE 2: Exercise durations (min/week) of the groups according to the weeks.

TABLE 2: Comparison of the clinical outcome between 2 groups.

	Group 1 X̄±SD	Group 2 X̄±SD	p value
First BASDAI score	3.93±1.58	3.12±1.22	0.271
Last BASDAI score	3.23±1.25	3.11±1.29	0.476
p value in repeated measurements:	**<0.001**	0.745	
Change in BASDAI scores	0.64±0.67	0.01±0.08	<0.01
Initial exercise duration (min/week)	19.79±31.04	26.37±45.82	0.868
Average exercise duration of 12 weeks (min/week)	56.62±52.91	25.00±38.42	0.12
Exercise duration in the last week (min/week)	70.20±64.88	24.35±39	0.03
p^a	**<0.001**		
p^b	**<0.001**	1.00	
The initial number of analgesics taken per week	4.29±3.34	3.93±3.09	0.548
Average of 12 weeks-number of analgesics taken per week	3.82±3.09	4.03±3.04	0.785
Number of analgesics taken per week at the end of the study	3.25±2.83	4.13±3.19	0.300
p^a	**0.034**		
p^b	**0.004**	0.305	

BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; SD: Standard deviation; p^a: p value in repeated measurements (between an average of 12 weeks and baseline), p^b: p value in repeated measurements (between the end of study and baseline), p<0.05 is statistically significant.

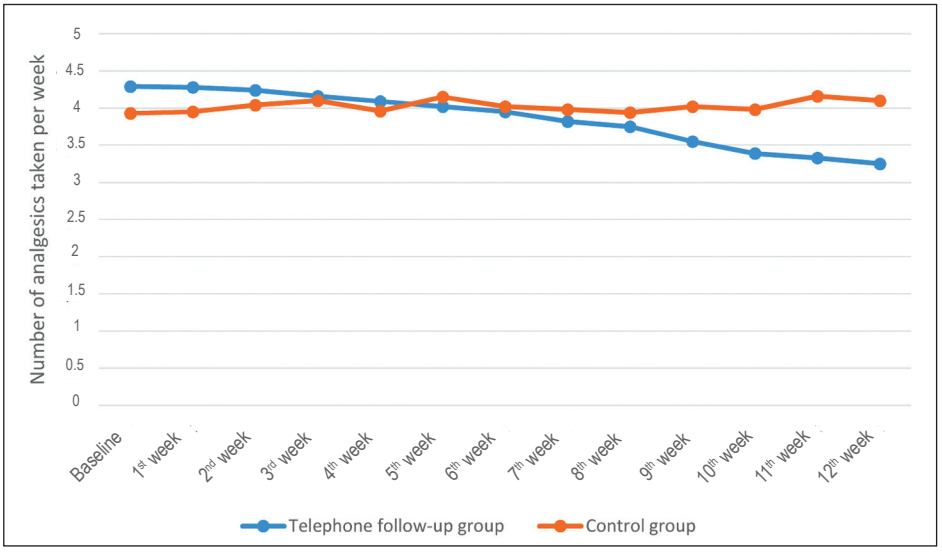

FIGURE 3: Weekly number of analgesics received by the groups.

TABLE 3: Exercise durations of the patients in Group 1 according to the disease activities and the drugs they used.

Group 1	Initial exercise duration (min/week) X̄±SD	Exercise duration in the last week (min/week) X̄±SD	p value in repeated measurements
TNF (n=14)	16.07±22.71	82.85±60.11	**0.002**
Non-TNF (n=10)	25.00±40.82	52.50±70.28	**0.027**
p value	0.796	0.212	
Patients with initial BASDAI<4	13.18±21.00	58.18±59.34	**0.012**
Patients with initial BASDAI≥4	26.66±38.86	85.41±70.53	**0.008**
p value	0.487	0.449	

SD: Standard deviation; TNF: Tumor necrosis factor; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; p<0.05 was statistically significant.

DISCUSSION

According to various guidelines, exercise therapy is a must-have treatment for AS patients.[10-13] In this study, it was determined that the average of 12 weeks and the exercise duration of the last week were longer than the first week in patients with AS who applied the telephone follow-up system. It has also been shown that disease activity and the amount of analgesics taken are reduced.

Beneficial effects of exercises on the range of motion, spinal mobility, pain level, cardiovascular system, osteoporosis, balance, functional and psychological status have been demonstrated in patients with AS.[13,27,28] Adherence to exercise programs is considered to be central to the therapeutic success of exercise.[14] As with many chronic diseases, treatment adherence is a common problem in AS.[9,14] It has been reported that approximately 60% of patients with rheumatic diseases do not reach the recommended physical activity level.[29,30] Arturi et al. used Compliance Questionnaire on Rheumatology and the Exercise Attitude Questionnaire-18 (EAQ-18) in their study and reported low exercise compliance in AS.[9] Unfortunately, there is no Turkish validity and reliability scale to evaluate exercise-related compliance and attitude in our country. Therefore, we made an evaluation based on the weekly exercise duration of the patients.

Compliance with exercise programs can be affected by many personal and interventional factors. Low self-efficacy, depression, and pain have been shown to reduce exercise compliance. The mode and type of exercise interventions (such as patient education, supervised exercise sessions, and goal setting) have been reported to improve adherence.[14]

Hidding et al. divided the participants into 2 after 9 months of supervised group physiotherapy (3 hours per week; 1-hour physical training, 1-hour sports activities, and 1-hour hydrotherapy). One group continued with supervised group physiotherapy, while the other group was given a home exercise program. They showed that those who went to the home exercise program did significantly less exercise than those who continued with supervised group physiotherapy and that the patient stopped exercising significantly. They recommended supervised group physiotherapy to increase exercise compliance in AS.[31]

Sweeny et al. divided patients with AS into 2 groups to evaluate the effect of a home-based self-care package (containing exercise). They gave stickers, an exercise progress wall chart, educational booklet, and an exercise video to the first group. There was no intervention for the control group. Self-reported exercise levels, a trend for improvement, and self-efficacy for exercise in function significantly increased in the intervention group compared to the control group.[32]

Barlow and Barefoot examined the effect of group patient education on psychological well-being, self-efficacy, and home exercise performance. They gave a group a 2-day self-management, a guidebook with motivation, hydrotherapy course, exercise, and education. There was no intervention for the control group. The self-management course improved psychological well-being and self-efficacy in 6 months. There were improvements in-home exercises at 3 weeks but not maintained at 6 months.[33]

A systematic review and meta-analysis of Sieczkowska et al. reported that home-based physical activity improves pain, quality of life, and functional capacity in autoimmune rheumatic diseases. Additionally, they found home-based physical activity interventions to be as effective as centre-based interventions for all investigated outcomes.[30] In this study of Sieczkowska et al., it was determined that phone calls and exercise diaries were mostly used to monitor the exercises. However, some researchers have also used e-mail or heart rate logs.[30]

Fang et al. gave patients with AS a home-based exercise program for 6 months. They made phone calls to the patients every 2 weeks. Monthly sessions were provided with a physical therapist to receive exercise instructions. As a result, they determined that this system increased spinal mobility, physical function, and quality of life compared to the control group.[34]

Taspinar et al. compared home-based exercises with hospital-based exercises in patients with AS. They found hospital-based exercises to be superior in terms of the Bath Ankylosing Spondylitis Metrology

Index (BASMI) and Hospital Anxiety and Depression Scale-Anxiety scores.[35]

Rodríguez-Lozano et al. gave a 2-hour information session about the disease and an unsupervised physical activity program at home to a group of AS patients. There was more improvement in Ankylosing Spondylitis Quality of Life, visual analogue scale for total pain and patient's global assessment scores in this group compared to the control group.[36]

The beneficial effects of methods such as telephone calls, telephone messages, mobile health technology, and telemedicine have been demonstrated in increasing patient compliance in some diseases.[15-17] However, there are very limited studies in the literature in which the telephone follow-up method is used to increase exercise compliance in AS patients. This study has shown that the telephone follow-up system can be a good alternative to increase compliance in AS. Thus, the disease activities of the patients can be improved, and the use of analgesics and health expenses can be reduced. In this study, although mixed random linear effects analysis could not show a significant effect of the telephone follow-up system on the exercise duration, as a result, the final exercise duration was approximately 3 and a half times and the 12-week exercise duration was tripled in the telephone follow-up system group compared to the baseline. However, there was no increase during exercise in the control group. Although the exercise duration increased three and a half times at the end of 12 weeks, no significant change was detected in the MLM analysis, which may be due to the following: weekly course is compared in the MLM analysis. Therefore, although the telephone follow-up system causes a relatively small and slow change that MLM analysis cannot detect in the weekly course, it ultimately leads to a significant increase compared to the base-line at the end of the 12-week period. This result shows that the telephone follow-up system has a slow effect and that it should be applied for at least 12 weeks in order to give a beneficial result. The different results in these 2 analyzes may also be due to the drop out of 6 patients in Group 1 and 1 patient in Group 2. Patients with drop out may have less exercise compliance and less weekly exercise duration, and patients with higher pain and disease activity. Therefore, disruption of the initial randomization with drop outs may lead to a bias in evaluating patients with better exercise compliance for Group 1. Unlike dependent sample tests that exclude drop outs, MLM analysis can predict missing data at the final evaluation point based on available data. Therefore, the data of those who drop out with MLM can also be used. As a result, drop outs may be another reason for the inconsistency between MLM analysis and Wilcoxon test results.

In addition, in the present study, it was found that the effect of the telephone follow-up system in increasing exercise compliance was not affected by the disease activity or the treatment received. In other words, exercise compliance increased both in patients with high disease activity and in patients with low disease activity. In addition, exercise compliance increased in both patients receiving TNF and those using drugs other than TNF. In cases such as pandemics where social distance is required, the telephone follow-up system may be a safer method for infection than methods such as supervised group physiotherapy.

The study has some limitations. In this study, only the duration of the exercise they performed was asked to evaluate the patients' compliance. A scale could not be used since there was not any in Turkish scale. Another limitation of this study is that functional evaluations of the patients were not performed. In this study, positive effects of telephone tracking system on exercise duration and BASDAI scores were shown. However, the relationships between the telephone follow-up system and the structural inabilities or disabilities were not evaluated, and scales such as the Short Form-36 health survey questionnaire, BASMI, and BASFI were not used. It may be suggested to investigate this issue in future studies. The third limitation of this study is that when evaluating the extent of analgesics used by the patients, the number of tablets and/or capsules was evaluated. Patients have been released regarding the type of analgesic they use, and not all analgesics show the same effect. In addition, there were no long-term results in the study. In the present study, 6 patients in Group 1 and 1 patient in Group 2 left the study process. The patients in Group 2 were evaluated only at the beginning and end of the study, while the patients in Group

1 answered the phone every week and reported the duration of the exercise they did. Six patients in Group 1 stopped responding to the phone after a certain week while the study was ongoing. Patients who did not answer the phone for three consecutive weeks were excluded from the study. Calling for longer periods instead of calling every week may reduce dropouts. This situation should be taken into consideration in future studies. In addition, one of the limitations is that the clinician who evaluated the patients was not blinded to the study groups. Despite these limitations, we think this study is critical because it is the first study to examine the effect of telephone call method on exercise compliance and disease activity.

CONCLUSION

The telephone follow-up system increases the compliance of the patients to the exercise and decreases the disease activity and the use of analgesics. Further studies on this subject are needed, with more patients, longer follow-up periods, and functional evaluation.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

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